

03/15/01

Q3-16-01

JCO9 Rec'd PCT/PTO 1 5 MAR 2001 PCT

J198 U.S. PTO

PTO-1590  
(1-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

M41.1

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/787244

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 USC § 371

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/US99/21049

14 September 1999

16 September 1998

TITLE OF INVENTION

Combined Stimulation of Ventral and Dorsal Sacral Roots for Control of Bladder Function

APPLICANT(S) FOR DO/EO/US

Bhadra et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- 1 ☒ This is a **FIRST** submission of items concerning a filing under 35 USC § 371 ☐
- 2 ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC § 371 ☐
- 3 ☒ This is an express request to begin national examination procedures (35 USC § 371(f)) ☐ The submission must include items (5), (6), (9) and (21) indicated below ☐
- 4 ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31) ☐
- 5 ☒ A copy of the International Application as filed (35 USC § 371(c)(2)) ☐
- a ☐ is attached hereto (required only if not communicated by the International Bureau) ☐
- b ☐ has been communicated by the International Bureau ☐
- c ☒ is not required, as the application was filed in the United States Receiving Office (RO/US) ☐
- 6 ☐ An English language translation of the International Application as filed (35 USC § 371(c)(2)) ☐
- a ☐ is attached hereto ☐
- b ☐ has been previously submitted under 35 USC § 54(d)(4) ☐
- 7 ☒ Amendments to the claims of the International Application under PCT Article 19 (35 USC § 371(c)(3)) ☐
- a ☐ are attached hereto (required only if not communicated by the International Bureau) ☐
- b ☐ have been communicated by the International Bureau ☐
- c ☐ have not been made; however, the time limit for making such amendments has NOT expired ☐
- d ☒ have not been made and will not be made ☐
- 8 ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 USC § 371(c)(3)) ☐
- 9 ☒ An oath or declaration of the inventor(s) (35 USC § 371(c)(4)) ☐
- 10 ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 USC § 371(c)(5)) ☐
- Items 11 to 20 below concern document(s) or information included:**
- 11 ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98 ☐
- 12 ☐ An assignment document for recording ☐ A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included ☐
- 13 ☐ A FIRST preliminary amendment ☐
- 14 ☐ A SECOND or SUBSEQUENT preliminary amendment ☐
- 15 ☐ A substitute specification ☐
- 16 ☐ A change of power of attorney and/or address letter ☐
- 17 ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter2 and 35 USC § 321 - 1.825 ☐
- 18 ☐ A second copy of the published international application under 35 USC § 54(d)(4) ☐
- 19 ☐ A second copy of the English language translation of the international application under 35 USC § 54(d)(4) ☐
- 20 ☐ Other items or information: ☐

US/APP/INT/STN/NO/PTO/US99/37 CFR 1(3)

097787244

INTERNATIONAL APPLICATION NO.  
PCT/US99/21049ATTORNEY'S DOCKET NUMBER  
M41.121 ☒ The following fees are submitted:

CALCULATIONS PTO USE ONLY

**BASIC NATIONAL FEE (37 CFR 1.482 (a) (1) - (5)):**Neither international preliminary examination fee (37 CFR 1.482)  
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO  
and International Search Report not prepared by the EPO or JPO ☐ \$1000.00International preliminary examination fee (37 CFR 1.482) not paid to  
USPTO but International Search Report prepared by the EPO or JPO ☐ \$860.00International preliminary examination fee (37 CFR 1.482) not paid to USPTO  
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ☐ \$710.00International preliminary examination fee (37 CFR 1.482) paid to USPTO  
but all claims did not satisfy provisions of PCT Article 33(1)-(4) ☐ \$690.00International preliminary examination fee (37 CFR 1.482) paid to USPTO  
and all claims satisfied provisions of PCT Article 33(1)-(4) ☐ \$100.00**ENTER APPROPRIATE BASIC FEE AMOUNT =**

\$ 690

Surcharge of \$130.00 for furnishing the oath or declaration later than  
months from the earliest claimed priority date (37 CFR 1.492(e)) ☐ 20 ☐ 30

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	18 - 20 =		x \$18.00	\$ ---
Independent claims	2 - 3 =		x \$80.00	\$ ---
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$

**TOTAL OF ABOVE CALCULATIONS =**☒ Applicant claims small entity status ☐ See 37 CFR 1.27 ☐ The fees indicated above  
are reduced by 1/2 ☐

\$ -345

**SUBTOTAL =**

\$ 345

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30  
months from the earliest claimed priority date (37 CFR 1.492(f)) ☐

\$

**TOTAL NATIONAL FEE =**

\$ 345

Fee for recording the enclosed assignment (37 CFR 1.21(h)) ☐ The assignment must be  
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) ☐ \$40.00 per property +

\$

**TOTAL FEES ENCLOSED =**

\$ 345

Amount to be  
refunded:

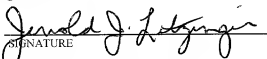
\$

charged:

\$

a ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed ☐b ☒ Please charge my Deposit Account No 12-1677 in the amount of \$ 345 to cover the above fees ☐  
A duplicate copy of this sheet is enclosed ☐c ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any  
overpayment to Deposit Account No 12-1677 ☐ A duplicate copy of this sheet is enclosed ☐d ☐ Fees are to be charged to a credit card ☐ **WARNING:** Information on this form may become public ☐ Credit card  
information should not be included on this form ☐ Provide credit card information and authorization on PTO-2038 ☐**NOTE:** Where an appropriate time limit under 37 CFR 1.394 or 1.395 has not been met, a petition to revive (37 CFR  
1.337 (a) or (b)) must be filed and granted to restore the application to pending status ☐

SEND ALL CORRESPONDENCE TO

Jerrold J. Litzinger  
Sentron Medical, Inc.  
4445 Lake Forest Drive, Suite 600  
Cincinnati, OH 45242

Jerrold J. Litzinger

NAME

29402

REGISTRATION NUMBER

**COMBINED STIMULATION OF VENTRAL AND DORSAL SACRAL  
ROOTS FOR CONTROL OF BLADDER FUNCTION****CROSS REFERENCE TO RELATED APPLICATIONS**

This is a utility patent application taking priority from provisional patent application 60/100,524, filed September 16, 1998, which is incorporated herein by reference.

**BACKGROUND OF THE INVENTION****1. Field of Invention**

This invention relates generally to selective nerve stimulation for bladder control, and, in particular, to a technique by which micturition can be achieved in spinal cord injured patients without dorsal root section.

**2. Description of the Prior Art**

Retention of urine, leading to complications such as urinary tract infection and urinary calculi, remains a major factor leading to morbidity in spinal cord injured patients. In high cord injury, with upper motor neuron damage, the lower nerve pathways to the bladder are intact. The aim of micturition control in these individuals is to enable them to contract the bladder musculature without activating structures in the urethra that may impede urine flow. The procedure should leave an acceptable post-void residual volume within the bladder and should also be able to prevent overflow incontinence.

The difference in the size of the nerve fibers to the bladder or bowel and the urethral or anal sphincter allows the development of techniques to selectively activate the nerves to the bladder and bowel without the activation of the  
5 sphincters.

Previously, electrical stimulation has been applied to control the bladder and bowel. The previous attempts have focused on three techniques: direct stimulation of the detrusor muscle, activation of the detrusor by stimulation of the conus  
10 medullaris, and activation of the detrusor by sacral root or nerve stimulation with extensive dorsal rhizotomy. All three of these methods suffer from the same problem. They all cause contraction of the bladder to expel urine concurrently with contraction of the external urethral sphincter blocking urine flow. The rhizotomy technique also results in the loss of erection for the male. It would be advantageous  
15 if contraction of the sphincter could be selectively blocked.

Techniques available for blocking nerve impulses are discussed, for example, in "A Technique for Collision Block of Peripheral Nerve: Single Stimulation Analysis", van den Honert and Mortimer, IEEE Transactions on Biomedical Engineering, Volume  
20 BME-28, No. 5, May 1981, pages 373-378, and "Generation of Unidirectionally Propagated Action Potentials in a Peripheral Nerve by Brief Stimuli", van den Honert and Mortimer, Science, Volume 206, December 1979, pages 1311-1312. With the van den Honert and Mortimer techniques, a nerve impulse or action potential is generated which travels toward the brain. When the artificially generated nerve

impulse meets a motor impulse travelling from the brain, the motor impulse is collision blocked. That is, the artificially generated action potential cancels the motor action potential. If one were to apply the van den Honert and Mortimer techniques, it could be used to cause concurrent relaxation of both the bladder

5 contracting muscles and the urethral sphincter.

Sacral nerve stimulation for electrical control of bladder function has been attempted for many years; however, virtually all attempts have been plagued by problems associated with co-activation of contractile structures in the urethra that

10 impede urine flow. One such attempt is described in U.S. Patent No. 4,607,639, which issued to Tanagho, et al. This patent describes a technique in which the sacral nerves are separated to isolate the ventral and dorsal roots thereof, and the inferior somatic nerve S1 is sectioned to isolate the external sphincter on one side. The dorsal root of S2 is then sectioned unilaterally to isolate the sensory function

15 thereof. An electrode is positioned on the S3 sacral nerve to stimulate the detrusor muscles of the bladder. However, it is suggested that sphincter response may be reflexly produced using this technique, and mentions the necessity for the rhizotomy of the dorsal roots.

20 U.S. Patent No. 5, 199,430 teaches a system for selectively arresting propagation of action potentials in large diameter fibers without arresting propagation in small diameter nerve fibers using a quasitrapezoidal waveform. This waveform, which is disclosed in U.S. Patent No. 4,608,985, and its stimulation scheme made it possible to install electrodes on the sacral roots that could

differentially activate the small fibers to the detrusor and rectum without activating the large fibers to the sphincter, thus allowing bladder and bowel activation without the sphincter tone being raised. However, this procedure often involved dorsal rhizotomy to minimize any reflexogenic response.

The present invention contemplates a new technique for bladder function control in which a dorsal rhizotomy is unnecessary.

## SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a system and method for inducing micturition in spinal cord injured patients.

It is a further object of the present invention to provide a method of controlling bladder draining by stimulating nerve cuff electrodes implanted on the sacral motor roots and also the sacral sensory roots.

It is a still further object of the present invention to provide a method of efficiently voiding the bladder of a patient without performing a dorsal rhizotomy.

These and other objects are accomplished in the present invention by a method and system for selectively controlling activation of a patient's bladder by applying trains of quasitrapezoidal pulses with appropriate current amplitudes on both the ventral and dorsal sacral roots to subdue urethral reflexes and enhance voiding.

## BRIEF DESCRIPTION OF THE DRAWINGS

5           FIG. 1 schematically illustrates the placement of electrodes for controlling the bladder in the present invention;

          FIG. 2 is a graphic representation showing average voided volume from different combinations of stimulus;

10           FIG. 3 is a graphic representation showing average voided volume when combined dorsal and ventral root stimulation is used; and

          FIG. 4 illustrates a stimulation scheme which may be used for combined  
15 stimulation of the dorsal and ventral roots in the present invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20           Referring now to FIG. 1, there is shown an illustrative embodiment of the present invention within the environment of the human body. Kidney 10 is connected to the bladder 12 via the ureter 14, which carries away urine from kidney 10 to bladder 12. Urine is expelled from the body through bladder neck 16 and urethra 18 and out from urethral sphincter 20. Bladder 12 and sphincter 20 function  
25 is controlled by action potentials traveling from spinal cord 19 primarily, but not limited to, on a pair of sacral roots 21 which consists of a segment of ventral sacral roots 22 and a segment of dorsal sacral roots 23. Dorsal roots 23 are primarily

sensory (afferent) to transmit sensation to spinal cord 19, while ventral roots 22 primarily transmit motor pulses (efferent) from spinal cord 19 to bladder 12 and sphincter 20. Although illustrated as being separated, the dorsal and ventral roots for each nerve are, in fact, normally joined together and their fibers mixed to progress as a single trunk.

Ventral roots 22 include nerve bundles 22a which include larger diameter nerve fibers and nerve bundles 22b which include smaller diameter fibers. Larger fibers 22a connect between spinal cord 19 and sphincter 20, while smaller fibers 22b connect between spinal cord 19 and bladder 12. Action potentials flowing along larger fibers 22a cause sphincter 20 to contract, blocking the outlet from urethra 18. When the bladder is to be emptied, the flow of action potentials through fibers 22a is stopped, allowing sphincter 20 to relax.

Smaller fibers 22b usually carry no action potentials until the person desires to evacuate the bladder; action potentials are then sent along fibers 22b concurrently with the stopping of action potentials along fibers 22a, causing sphincter 20 to relax and allowing bladder neck 16 to open concurrently with bladder 12 muscles contracting, thus expelling urine.

Spinal cord injuries and various other medical conditions can cause a loss of control of the bladder function. To reinstitute this control, a cuff electrode 30 can be mounted surrounding sacral ventral root 22. Cuff electrode 30, which is preferably a self-curling spiral electrode that is biased to curl around the selected root and is



described in U.S. Patent No. 4,602,624, is configured to accommodate nerves of varying diameters and can electrically excite action potentials on smaller fibers 22b while blocking naturally occurring and electrically activated action potentials from travelling downstream on larger fibers 22a. An example of this procedure is

5 described in detail in U.S. Patent No. 5, 199,430, which issued in April 6, 1993, and is hereby incorporated by reference in its entirety.

The present invention also includes an additional cuff electrode 32 which is implanted on a dorsal sacral root 23. Application of trains of quasitrapezoidal

10 pulses, which are described and taught in U.S. Patent No. 4,608,985, which patent is incorporated herein by reference, that have appropriate current amplitudes and are applied concurrently to electrodes 30 and 32 to stimulate the dorsal and ventral roots can result in the voiding of bladder contents without increasing sphincter pressures. A controller 34 is electrically coupled to electrodes 30 and 32 to provide

15 the necessary signals for this desired bladder control.

Several experiments were conducted to confirm that combined dorsal and ventral root stimulation provides an effective low pressure bladder evacuation without requiring dorsal rhizotomy.

## 20 EXPERIMENT 1

Combined sensory and motor stimulus was applied to an animal under 2.5% halothane inhalation anesthesia. An efferent motor stimulus was applied by a spiral

25 nerve cuff electrode implanted on S2 motor roots. Either a quasitrapezoidal,

balanced biphasic, 20 Hz pulse, with current amplitude set at a volume determined to selectively block sphincter activity, or a conventional rectangular supra-threshold stimulus was used. The efferent sensory stimulus was applied to the S2 dermatome with surface electrodes using a 20 Hz balanced biphasic rectangular pulse at 10 to 15 ma. The surface stimulus was varied to be continuous or intermittent (1 second on/1 second off). The bladder was filled before each trial run with 60 ml of sterile saline.

FIG. 2 shows the average volume of fluid voided during a 10 second pulse train for each combination of stimulus trains. The results show that a combination of selective motor root activation by a quasitrapezoidal pulse train and intermittent surface stimulation to the S2 dermatome enhanced bladder emptying.

## EXPERIMENT 2

Combined sensory and motor stimulus was applied to an animal under 2.5% halothane inhalation anesthesia. The motor stimulus was applied by a spiral nerve cuff electrode implanted on the S2 motor roots. A quasitrapezoidal, balanced biphasic, 20 Hz pulse, with current amplitude set at a value determined to selectively block sphincter activity, was used. The sensory stimulus was applied to S1, S2, or S3 dermatome with surface electrodes using a 20 Hz balanced biphasic rectangular pulse at 10 to 15 ma. The intermittent surface stimulation was varied to be either 1 second on/1 second off or 0.5 seconds on/0.5 seconds off. The tests were randomized for stimulus combinations. The test results show that bladder emptying

was enhanced only when the combined sensory stimulus was applied to the S2 dermatome. The 1 second on/1 second off intermittent pattern was more effective than the 0.5 seconds on/0.5 seconds off pattern.

## 5 EXPERIMENT 3

Combined stimulation of the dorsal and ventral sacral roots was applied to an animal by implanting spiral nerve cuff electrodes on the sacral ventral motor roots at S2 and S3, while leaving the dorsal roots intact and implanting a spiral nerve cuff electrode on one dorsal S2 root. The ventral sacral roots were stimulated with quasitrapezoidal pulse trains at 20 Hz with current amplitudes sufficient to selectively activate the bladder or with 20 Hz conventional rectangular pulses. At the same time, a 20 Hz intermittent stimulus, 1 second on/ 1 second off was applied to the S2 dorsal root.

Table 1 shows the average results from three trials for each stimulus pattern. For 10 seconds of motor stimulation, an average increase of 66% in flow rate was observed during combined motor and sensory stimulation, while FIG. 3 shows the average volumes voided.

**TABLE 1**

Pulse Type	Qmax	V(ml)	Pv (Qmax)	Pu (Qmax)	Pv max	Pu max
20 Hz R	2.3	6.0	50.0	40.0	117.5	160.0
20 Hz Q	2.4	7.0	78.8	57.5	111.3	99.4
Aff + 20 Hz Q	4.0	27.0	59.2	51.7	85.0	80.0

Q <sub>max</sub>	= Average maximum flow rate in ml/sec
V(ml)	= Average voided volume in ml
P <sub>v</sub> (Q <sub>max</sub> )	= Maximum bladder pressure in cm of water at maximum flow
5 Pu (Q <sub>max</sub> )	= Average sphincter pressure in cm of water at maximum flow
P <sub>v</sub> max	= Maximum bladder pressure in cm of water
Pu max	= Maximum sphincter pressure in cm of water

10 FIG. 4 illustrates the stimulus pattern for the combined dorsal and ventral root stimulation of the present invention. An intermittent pulse train 100 is applied to dorsal root 23 via cuff electrode 32, while a continuous pulse train 102 is simultaneously applied to ventral root 22 via cuff electrode 30. In this manner, low pressure bladder activation can be achieved by modulating the reflexes associated with the neural system for micturition control and eliminate the need for dorsal rhizotomies.

15

Pulse train 100 preferably consists of pulses delivered at a frequency of 10 to 35 Hz, with each pulse having a nominal amplitude of less than 1 ma and a pulse duration of 10 to 100  $\mu$ sec. Pulse train 100 is generated intermittently, with a pattern of 0.25 to 1 second on/ 0.25 to 1 second off. Pulse train 102 preferably consists of a continuous series of quasitrapezoidal pulses of 350 to 500  $\mu$ sec duration and a nominal amplitude of 1 ma delivered at a frequency of 15 to 30 Hz.

20

25 While the invention has been shown and described in terms of several preferred embodiments, it will be understood that this invention is not limited to

these particular embodiments and that many changes and modifications may be made without departing from the true spirit and scope of the invention as defined in the appended claims.

**WHAT IS CLAIMED IS:**

1. A method for controlling bladder discharge in a patient, comprising the steps  
5 of:

coupling a first electrode to a sacral ventral root of said patient;

coupling a second electrode to a sacral dorsal root corresponding to  
10 said ventral root of said patient;

and transmitting a series of stimulus pulses to said first and second  
electrodes simultaneously to cause discharge of the bladder

- 15 2. The method of claim 1 wherein said first electrode comprises a self-sizing cuff  
electrode.

3. The method of claim 1 wherein said second electrode comprises a self-sizing  
cuff electrode.

- 20 4. The method of claim 1 wherein said second electrode comprises a surface  
electrode.

5. The method of claim 1 wherein said stimulus pulses transmitted to said first  
25 electrode comprise a quasitrapezoidal pulse train at 20 Hz.

6. The method of claim 1 wherein said stimulus pulses transmitted to said first electrode comprise a conventional rectangular pulse train at 20 Hz.
7. The method of claim 1 wherein said stimulus pulses transmitted to said second electrode comprise an intermittent pulse train at 20 Hz having a one second on/ 1 second off pattern.
8. The method of claim 1 wherein said first and second electrodes are applied to the dorsal and ventral roots of the S3 sacral nerve.
9. The method of claim 1 wherein said stimulus pulses transmitted to said second electrode have a nominal amplitude of less than 1 ma and a pulse duration of 10 to 100  $\mu$ sec.
10. The method of claim 1 wherein said stimulus pulses transmitted to said first electrode have a nominal amplitude of 1 ma and a pulse duration of 350 to 500  $\mu$ sec.
11. An apparatus for the control of bladder function in a patient by combined stimulation of ventral and dorsal sacral roots, said apparatus comprising:
- a first electrode, applied to a ventral sacral root of a patient;
- a second electrode, applied to a dorsal sacral root corresponding to said ventral sacral root;

and control means, electrically coupled to said first and second electrodes, for generating a series of stimulus pulses simultaneously to said first and second electrodes sufficient to cause the bladder of said patient to contract, whereby emptying said bladder.

12. The apparatus of claim 11, wherein said first electrode comprises a self-sizing cuff electrode.

13. The apparatus of claim 11, wherein said second electrode comprises a self-sizing cuff electrode.

14. The apparatus of claim 11, wherein said second electrode comprises a surface mounted electrode.

15. The apparatus of claim 11, wherein said stimulus pulses generated to said first electrode by said control means comprises a quasitrapezoidal pulse train at 20 Hz.

16. The apparatus of claim 11, wherein said stimulus pulses generated to said second electrode by said control means comprise an intermittent pulse train pattern of 1 second off/ 1 second on.



17. The apparatus of claim 11, wherein said stimulus pulses generated to said first electrode by said control means have a nominal amplitude of 1 ma and a pulse duration of 350 to 500  $\mu$ sec.

5 18. The apparatus of claim 11, wherein said stimulus pulses generated to said second electrode by said control means have a nominal amplitude of less than 1 ma and a pulse duration of 10 to 100  $\mu$ sec.

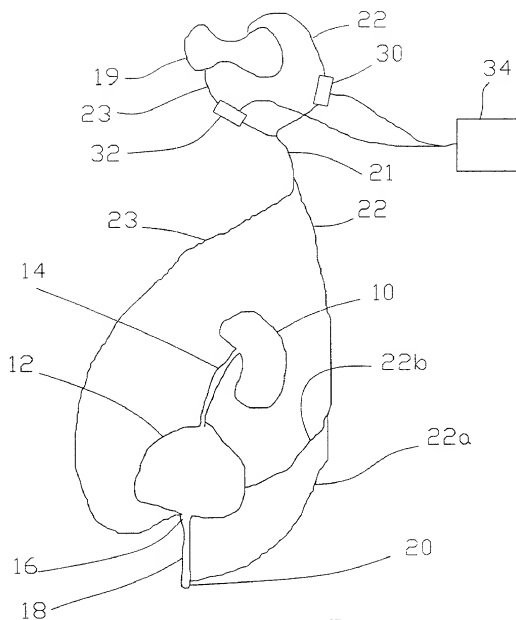


FIG. 1

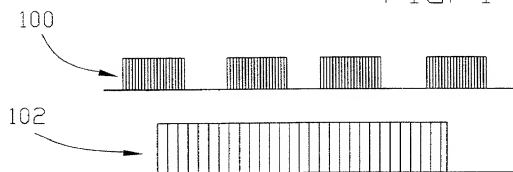


FIG. 4

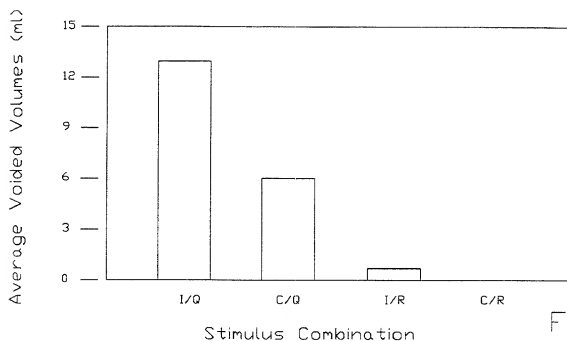


FIG.2

Average Voided Volumes During a 10 Second Pulse Train

I/Q = Intermittent surface stimulation with Quasitrapezoidal motor pulses

C/Q = Continuous surface stimulation with Quasitrapezoidal motor pulses

I/R = Intermittent surface stimulation with Rectangular motor pulses

C/R = Continuous surface stimulation with rectangular motor pulses

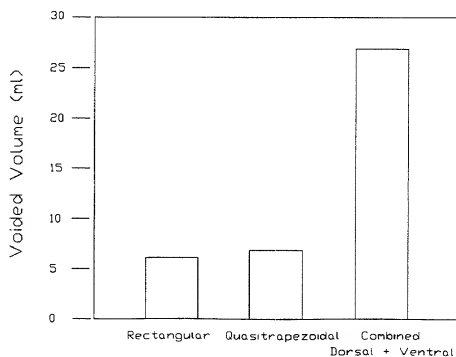


FIG.3

Please type a plus sign (+) inside this box → ☐

PTO/SB/01 (10-00)

Approved for use through 10/31/2002 OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

# **DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing **OR** ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

**Attorney Docket Number** M41.1

**First Named Inventor** BHADRA

## **COMPLETE IF KNOWN**

**Application Number** /

**Filing Date**

**Group Art Unit**

**Examiner Name**

## **As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

COMBINED STIMULATION OF VENTRAL AND DORSAL SACRAL ROOTS FOR THE CONTROL OF BLADDER FUNCTION

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 09/14/1999 as United States Application Number or PCT International

Application Number PCT/US99/21049 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES NO
			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
60/100542	09/16/1998	

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

**DECLARATION — Utility or Design Patent Application**

Direct all correspondence to.

Customer Number  
or Bar Code Label

25742

OR ☐

Correspondence address below

Name

Address

Address

City

State

ZIP

Country

Telephone

Fax

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR :

☐ A petition has been filed for this unsigned inventor

Given Name

NARENDRA

Family Name

BHADRA

(first and middle (if any))

Inventor's  
Signature

Date

03/07/01

Residence: City

CLEVELAND HEIGHTS

State OH

Country US

Citizenship IN

Mailing Address

2075 COVENTRY ROAD

Mailing Address

City CLEVELAND HEIGHTS

State OH

ZIP 44118

Country US

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name

J. Thomas

Family Name

Mortimer

(first and middle (if any))

Inventor's  
Signature

Date

7 March '01

Residence: City

Chagrin Falls

State OH

Country US

Citizenship US

Mailing Address

13753 County Line Road

Mailing Address

City Chagrin Falls

State OH

ZIP 44022

Country US

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

Please type a plus sign (+) inside this box → ☐

PTO/SB/02A (11-00)  
Approved for use through 10/31/2002. OMB 0851-0032  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## DECLARATION

**ADDITIONAL INVENTOR(S)**  
**Supplemental Sheet**  
Page 1 of 1

**Name of Additional Joint Inventor, if any:**

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Family Name or Surname

Volker

Grunewald

Inventor's  
Signature

Date

07/16/2001

Residence: City

Hannover

State

Country

DE

Citizenship

DE

Mailing Address

Konstanty-Gutschow Str. 8

Mailing Address

City 3000 Hannover

State

ZIP

Country

DE

**Name of Additional Joint Inventor, if any:**

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Family Name or Surname

Inventor's  
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

Mailing Address

City

State

ZIP

Country

**Name of Additional Joint Inventor, if any:**

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Family Name or Surname

Inventor's  
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

Mailing Address

City

State

ZIP

Country

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231